

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re U.S. Patent No. 7,435,742)	
)	
Issue Date: October 14, 2008)	Group Art Unit: 1625
)	
Inventor: Maria PRAT QUINONES et al.)	Examiner: RAHMANI, Niloofer
)	
Application No.: 10/518,496)	Conf. No. 4930
)	
§ 371 Date: September 19, 2005)	
)	
For: QUINUCLIDINE DERIVATIVES AND)	
PHARMACEUTICAL)	
COMPOSITIONS CONTAINING THE)	<u>VIA EFS-WEB</u>
SAME)	

BOX: PETITIONS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

**PETITION UNDER 37 C.F.R. § 1.181 REQUESTING REVIEW OF THE
DISMISSAL OF PATENTEE'S REQUEST FOR RECONSIDERATION OF PATENT
TERM ADJUSTMENT**

Patentee petition the Director under the provisions of 37 C.F.R. § 1.181 for review and reconsideration of the Decision on Request for Reconsideration of Patent Term Adjustment mailed by the Office of Petitions on September 30, 2009 ("the Decision").

PTA in Patentee's Previous Petition under 37 C.F.R. §1.705(d)

The United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 7,435,742 B2 ("the '742 patent") on October 14, 2008, with a patent term adjustment of

296 days. On November 12, 2008, Patentee filed a Post Grant Application for Patent Term Adjustment ("Petition") requesting an additional 26 days of patent term adjustment pursuant to the decision in *Wyeth v. Dudas*, 580 F. Supp. 2d 138 (D.D.C. 2008).

In the Petition, Patentee calculated the additional 26 days of patent term adjustment due to the period of delay under 37 C.F.R. §1.702(b) ("Three Year Delay") based, *inter alia*, on a previous Office's interpretation of the meaning of the date "the national stage commenced under 35 U.S.C. 371(b) or (f) in an international application" recited in 37 C.F.R. §1.703(b). According to previous Office practice, this date was taken to be as the date the requirements of Section 371 were fulfilled. As now acknowledged by the Office, the date the national stage commenced under Section 371 in an international application is the day after the expiration of the 30 months from the priority date of the application. Decision at p. 2, ¶ 2.

Based on this new interpretation of Rule 1.703(b), Office construed Patentee's Petition to request 298 extra days of Patent Term Adjustment ("PTA"), in addition to the 296 days already granted by the Office, for a total PTA value of 594 days. Decision at p. 3, ¶ 1. The 298-day period corresponds to the Three Year Delay period from December 22, 2007 (three years after application commencement date) to October 14, 2008, (patent issue date), assuming that the application commencement date is December 21, 2004. Decision at p. 2, ¶ 2, p. 3, ¶ 1. Patentee agrees with the Office's interpretation of Patentee's Petition as requesting a total PTA of 594 days (298 days additional to the 296 days calculated by the Office).

Statement of Facts

Based on the statements in the Decision, Patentee understands that Patentee and the Office agree on the following facts. The Three Year Delay period occurring from December 22, 2007, to October 14, 2008 is 298 days. The total value of the Office's examination delay before the three year anniversary of the application commencement date is 383 days. The total value of Applicant delay is 87 days.

Issue to be Decided in the instant §1.181 Petition

At issue in this petition, is whether the period of PTO examination delay occurring before the three year anniversary of the date the national stage commenced for the instant application (A delays, 383 days in this case) should be added to the PTO Three Year Delay under §1.702(b) (B delays, 298 delays) in order to obtain the total PTO delay (total delay, 681 days). There is no dispute that the Applicant delay (87 delays) should be subtracted from the total PTO delay to arrive at the final value of the PTA.

Patentee argues that in view of the *Wyeth* decision, the 383 days in A delays should be added to the 298 days of B delays because they do not overlap (i.e., they did not occur on the same calendar days). According to the Office's interpretation, there is an overlap of 298 days. Decision at p. 3, ¶ 3.

Arguments in Support of Petition

1. The Office is ignoring its duty under 35 U.S.C. § 2(b)(2)(a), to establish regulations "not inconsistent with the law."

The decision in *Wyeth* clearly stated that the method used by the Office to calculate Patent Term Adjustment by considering that A delays overlap with B delays and that Patentees only receive the greater of the two delays was inconsistent with

35 U.S.C. § 154(b)(1)(B). *Id.* at 142. Applying the *Wyeth* decision to the instant case, the 298 days of PTO delay under the three-year pendency rule provided by 35 U.S.C. § 154(b)(1)(B) should be counted in addition to the PTO examination delay of 383 days under the 14 month delay provided by 35 U.S.C. § 154(b)(1)(A)(i) offset by 87 days of Applicants' delay. Thus, the total of PTO patent term adjustment for the '742 patent based on delay is 594 days.

The PTO's argument in the Decision indicated that Patentee's calculation of the period of overlap was inconsistent with the PTO's interpretation of 35 U.S.C. 154(b)(2)(A) and 37 C.F.R. § 1.703(f). *See* Decision at page 3. More particularly, the PTO asserted that the entire period of PTO examination delay, and not only the period of PTO examination delay that occurred after the date that was three years after the actual filing date of the '742 patent, was the period of overlap between the delay provided by 35 U.S.C. § 154(b)(1)(A) and 35 U.S.C. § 154(b)(1)(B) under 35 U.S.C. § 154(b)(2)(A). Respectfully, such a position ignores the district court's decision in *Wyeth*.

Under 35 U.S.C. § 2(b)(2)(a), the PTO has a duty to establish regulations "not inconsistent with the law." In *Wyeth*, the district court explained the proper construction of the provisions of 35 U.S.C. § 154(b) for determining patent term adjustment. In accordance with *Wyeth*, the patent term adjustment for the '742 patent is 594 days, as set forth above. The PTO's refusal to implement the district court's decision regarding the proper statutory interpretation, or to at least hold requests for correction in abeyance while the *Wyeth* appeal is pending, is inconsistent with the current law and contrary to its duty to patentees eligible for patent term adjustment.

Request for Relief

Patentee respectfully requests that the Director grant a total Patent Term Adjustment of 594 days to the '742 patent based on the arguments presented above.

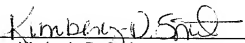
Patentee recognizes that the underlying legal issue in this petition will not become clear at least until the Federal Circuit decides the pending appeal in *Wyeth*. Therefore, alternatively, Patentee requests that the Director await the outcome of the *Wyeth* appeal before taking any action on the instant Patentee's petition under 37 C.F.R. § 1.181. Under this request, upon resolution of the appeal, Patentee requests that the Director exercise his supervisory authority to review and reconsider Patentee's Post Grant Application for Patent Term Adjustment and issue a decision on the petition that is consistent with the final outcome of the *Wyeth* appeal.

If there are any fees due in connection with the filing of this request, please charge such fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

Dated: November 24, 2009

By: 
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